

**. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**APR 4 1996**

Terry B. Stone  
Regulatory Affairs Manager  
Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, MO 63198

Dear Mr. Stone:

This is in regard to Monsanto Company's consultation with the Food and Drug Administration (FDA) Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition on genetically modified potatoes, specifically the following transformation events: ATBTO4-6, -27, -30, -31, and -36 (Newleaf<sup>TM</sup>, variety Atlantic); and SPBTO2-5 and -7 (Newleaf<sup>TM</sup>, variety Superior). According to Monsanto, these modified potato lines express a synthetic version of the *cryIIIA* gene, similar to the *cryIIIA* gene isolated from *Bacillus thuringiensis* var *tenebrionis*. The *cryIIIA* gene encodes the Bt protein, which is toxic to certain lepidopteran insects upon ingestion. Additionally, these modified potato lines also express the *kanR* (*nptII*) gene, derived from the prokaryotic transposon *Tn5*. The *kanR* gene encodes the APH(3')II (or NPTII) enzyme for aminoglycoside antibiotic resistance.

In February of 1993, Monsanto met with FDA to discuss their proposed safety and nutritional assessment of genetically modified potatoes. As part of bringing Monsanto's consultation regarding the above stated product(s) to closure, Monsanto submitted a summary assessment of potatoes containing transformation events ATBTO4-6, -27, -30, -31, and -36 and SPBTO2-5 and -7 on January 24, 1996.

These communications informed FDA of the steps taken by Monsanto to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that potatoes, derived from the new varieties, are not materially different in composition, safety, and other relevant parameters from potatoes currently on the market, and that the genetically modified potatoes do not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0033. This file will be maintained in the Office of Premarket Approval.

Based on the information Monsanto has presented, we have no further questions concerning potatoes from transformation events ATBTO4-6, -27, -30, -31, and -36 and SPBTO2-5 and -7 at this time.

However, as you are aware, it is Monsanto's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/S/

Alan M. Rulis, Ph.D.  
Director  
Office of Premarket Approval  
Center for Food Safety  
and Applied Nutrition

CC: HFS-200 HFS-205 HFS-226 HFS-235 HFS-246 HFS-247  
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HFS-206